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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,875	10/12/2000	Michifumi Tanga	TANGA2	5274

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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/601,875	TANGA ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7-10,12-16 and 22-42* is/are pending in the application.

4a) Of the above claim(s) *12 and 26-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7-10,13-16,22-24 and 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed 23 January 2004 in which claims 1, 2, 9, 10, 13, 14, 16 were amended and claim 42 was added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 24 October 2003, not reiterated below, are withdrawn in view of the amendments. New grounds for rejection are discussed.

Claims 1-2, 7-10, 13-16, 22-24 and 39-42 are under prosecution.

2. It is noted that "Listing of Claims, identifies Claim 8 as "previously presented" and Claims 9-10 as "currently amended". Claims 9-10 have each been marked up to replace "claim 1" with "claim 42" and to replace "introduced" with "coupled". It is further noted that Claims 8-10 are improperly amended from the previously presented claims to delete "a silane coupling agent". This deletion is improper because it is not reflected in the marked up version of the claims. For purposes of examination, Claims 8-10 are deemed to include the recitation "a silane coupling agent" because the claims have not been properly amended to reflect the deleted recitation.

3. In the previous office action the examiner stated:

Claims drawn to a substrate wherein the surface is modified to contain a polar radical selected from the group consisting of carboxyl, epoxy or amino and comprising a hydrocarbon wherein the radical is connected to the surface via a titanium coupling agent or aluminum coupling agent would be free of the cited prior art.

In response, Applicant submitted new Claim 42 reciting the above limitations. However, new Claim 42 is not limited to a substrate having DNA immobilized thereon. The examiner did not indicate that this limitation was required. However, without such limitations, the claim is encompassed by non-DNA prior art. Claim 42 and Claims 9-10 depending therefrom are discussed below.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-2, 7-10, 13-16, 22-24 and 39-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation "by binding a carboxyl (epoxy) radical to the substrate by setting the substrate into a solution containing a carboxyl radical with a hydrocarbon having from 1 to 10 carbon atoms" is added to the newly amended independent Claims 1, 13 and 16 from which all other pending claims depend. The specification teaches a carboxyl radical added to a substrate through a terminal hydroxyl wherein the hydroxyl has from 1 to 10 carbons (page 6, lines 11-16). The specification has been by the examiner. However, support for the newly claimed binding a carboxyl radical with a hydrocarbon having 1 to 10 carbons was not found.

It is noted that Applicant has not pointed to support for the instant amendments. It is suggested that Applicant point to supporting disclosures.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. ***APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).**

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 42, 9 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Santo et al (U.S. Patent No. 5,965,252, issued 12 October 1999.

Regarding Claim 42, 9 and 10, Santo et al disclose a substrate having a surface modified to contain a polar radical containing a hydrocarbon chain and a polar groups selected from epoxy and amino wherein the radical is connect through a titanium or aluminum coupling agent (Column 4, lines 30-32 and 46-53).

Claim Rejections - 35 USC § 102/103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 11, 13-16 and 25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chrisey et al (U.S. Patent No. 5,688,642, issued 18 November 1997) as defined by Sumiya et al (U.S. Patent No. 5,332,629, issued 26 July 1994).

Regarding Claim 1, Chrisey et al teach a solid state substrate for DNA immobilization (i.e. diamond) (Column 7, lines 24-28), wherein said substrate has a thermal conductivity ration of at least 0.1W/cm ° K as defined by Sumiya et al (Column 1, Table 1) wherein the surface of the substrate is modified by binding a chloride or hydroxyl radical (Column 7, lines 35-50) and wherein said substrate is used for immobilizing and amplifying DNA (Column 9, lines 22-27) wherein the substrate has a polar radical at a terminal on the surface of the

substrate (Column 7, lines 35-50 and Fig. 4-5) and wherein said polar radical is hydroxyl radical, epoxy radical or amino radical (Column 7, lines 35-50).

Furthermore, Chrisey et al teach the substrate wherein the radical is coupled to the substrate through a hydrocarbon having 1-10 carbons (Column 7, lines 2-14 and Fig. 5). While they illustrate an amino radical, they teach the terminal radical is a carboxyl (Column 7, lines 2-14 and 35-50).

The recitation "for amplifying DNA" in the preamble of Claim 1and the recitation "for amplifying and immobilizing DNA" in lines 3-4 of Claim 1 are recitations of intended use for the claimed substrate. The courts have stated that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). The intended use of the claimed substrate does not differentiate the claimed apparatus over the substrate of Chrisey et al.

The claim further recites the method steps by which the substrate is made. However, the courts have stated, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see **MPEP 2113**.

"The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, **the burden shifts to applicant to come forward with evidence**

establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) (The claims were directed to a zeolite manufactured by mixing together various inorganic materials in solution and heating the resultant gel to form a crystalline metal silicate essentially free of alkali metal. The prior art described a process of making a zeolite, which, after ion exchange to remove alkali metal, appeared to be "essentially free of alkali metal." The court upheld the rejection because the applicant had not come forward with any evidence that the prior art was not "essentially free of alkali metal" and therefore a different and unobvious product.).

"[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, **it is the patentability of the product claimed and not of the recited process steps which must be established**. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." In re Brown, 459 F.2d 531, 535.

In the instant case, the substrate of Chrisey et al provides the polar radical at the substrate surface as claimed (Fig.5). Therefore, because Chrisey et al disclose the structural components of the substrate that define the claimed substrate (product), the instantly claimed is the same as that of Chrisey et al.

The burden is on Applicant to show that the instantly claimed substrate is structurally either different from or non-obvious over that of Chrisey. It is suggested that Applicant provide factual evidence to support an allegation of non-anticipation or non-obviousness.

Regarding Claim 11, Chrisey et al teach said chip wherein DNA is immobilized to said substrate (Column 3, lines 20-25 and Column 7, lines 21-28).

Regarding Claim 13, Chrisey et al teach a solid state substrate having DNA immobilized thereon wherein said substrate is diamond and is chemically modified by binding a chloride or hydroxyl radical (Column 7, lines 21-50) and wherein said substrate is used for immobilizing and amplifying DNA (Column 9, lines 22-27).

Furthermore, Chrisey et al teach the substrate wherein the radical is coupled to the substrate through a hydrocarbon having 1-10 carbons (Column 7, lines 2-14 and Fig. 5). While they illustrate an amino radical, they teach the terminal radical is a carboxyl (Column 7, lines 2-14 and 35-50).

Regarding Claim 14, Chrisey et al teach said substrate having DNA immobilized thereon wherein said substrate has a polar radical at a terminal of the surface of the substrate (Column 7, lines 41-50).

Regarding Claim 15, Chrisey et al teach said substrate wherein said polar radical is hydroxyl radical, epoxy radical or amino radical (Column 7, lines 35-50).

Regarding Claim 16, Chrisey et al teach their chip is for amplifying and immobilizing DNA (Column 9, lines 9-27).

The recitation "for amplifying and immobilizing DNA" is functional language and does not describe the claimed substrate in terms of structure. The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114). Because "for amplifying and immobilizing DNA" does not describe structural components of the claimed substrate, the recitation does not distinguish the substrate over the prior art substrate.

Regarding Claim 25, Chrisey et al teach the substrate of Claim 15 wherein said polar radical is an epoxy radical and said epoxy radical is introduced to a surface of said substrate with a silane coupling agent (Column 7, lines 41-43).

Response to Arguments

10. Applicant argues that the substrates of Chrisey et al require organosilanes on the surface while the instantly claimed invention does not require the organosilanes of Chrisey et al.

The argument has been considered but is not found persuasive because the claims are drawn to a product i.e. a solid state substrate. The structural components of the claimed substrate include a diamond, synthetic diamond or diamond-like carbon substrate wherein said substrate is modified with a polar radical i.e. chloride, epoxy or hydroxyl radical. As stated above, Chrisey et al disclose the structural components of the substrate as claimed.

Applicant further argues that in contrast to Chrisey, the only coupling agents instantly claimed are titanium or aluminum. The argument has been considered but is not found persuasive because the above rejected claims are not limited to titanium and aluminum coupling agents. Hence, the argument is not commensurate in scope with the rejected claims.

Applicants are advised that arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965) (see MPEP 716.01(c).

Claim Rejections - 35 USC § 103

11. Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chrisey et al (U.S. Patent No. 5,688,642, issued 18 November 1997)as defined by Sumiya et al (U.S. Patent No. 5,332,629, issued 26 July 1994) in view of Fodor et al (U.S. Patent No. 5,800,992, issued 1 September 1998).

Regarding Claims 39-41, Chrisey et al teach a solid state substrate for DNA immobilization (i.e. diamond) (Column 7, lines 24-28), wherein said substrate has a thermal conductivity ration of at least 0.1W/cm ° K as defined by Sumiya et al (Column 1, Table 1) wherein the surface of the substrate is modified by binding a chloride or hydroxyl radical (Column 7, lines 35-50) and wherein said substrate is used for immobilizing and amplifying DNA (Column 9, lines 22-27) wherein the substrate has a polar radical at a terminal on the surface of the substrate (Column 7, lines 35-50 and Fig. 4-5) and wherein said polar radical is hydroxyl radical, epoxy radical or amino radical (Column 7, lines 35-50).

Chrisey et al do not teach the surface of the substrate is roughened. However, substrates having a roughened surface were well known in the art at the time the claimed invention was made as taught by Fodor et al (Column 37, line 65-Column 38, line 6). Specifically, Fodor et al teach a similar substrate for DNA immobilization wherein the substrate is modified by binding a hydroxyl radical (Column 37, lines 42-64 and Columns 43-44) and wherein the surface of the substrate is roughened (i.e. machined or etched) thereby increasing the surface area and increasing the density of reagent attachment (Column 37, line 65-Column 38, line 6). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the substrate surface of Chrisey et al by roughening the surface as taught by Fodor et al to thereby increase surface area of the substrate for the obvious benefits of increasing the density of reagent attachment and regent-binding as taught by Fodor et al (Column 37, line 65-Column 38, line 6).

Response to Arguments

12. Applicant argues that Fodor et al adds nothing to cure the deficiencies of Chrisey. The arguments have been considered but are not found persuasive for the reasons stated above regarding Chrisey.

13. Claims 2, 7, 8 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chrisey et al (U.S. Patent No. 5,688,642, issued 18 November 1997) in view of Kobashi (U.S. Patent No. 5,77,372, issued 7 July 1998).

Regarding Claims 2, 7, 8 and 22-24, Chrisey et al teach a solid state substrate for DNA immobilization (i.e. diamond) (Column 7, lines 24-28), wherein said substrate has a thermal conductivity ration of at least 0.1W/cm ° K as defined by Sumiya et al (Column 1, Table 1) wherein said substrate is used for immobilizing and amplifying DNA (Column 9, lines 22-27) wherein said substrate is diamond (Column 7, lines 24-28) wherein said substrate is chemically modified by binding a hydroxyl radical to the substrate (Column 7, lines 41-50) wherein said substrate has a polar radical at a terminal on the surface of the substrate (Column 7, lines 35-50 and Fig. 4-5) and wherein said polar radical is hydroxyl radical, epoxy radical or amino radical wherein the polar radical is connected on a surface through an ester linkage, an amide linkage or introduced with a silane coupling agent (Column 7, lines 35-50). Chrisey et al do not teach said polar radical is a carboxyl radical. However, Kobashi teaches a similar a solid state substrate wherein said substrate is chemically modified to have a polar radical at a terminal wherein the polar radical is selected from the group consisting of hydroxyl, carboxyl, epoxy and amino (Column 10, line 63-Column 11, line 11). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the chemical modification of substrates as taught by Chrisey et al by chemically modifying with a carboxyl radical as taught by Kobashi based on the teaching of Kobashi wherein hydroxyl, carboxyl, epoxy and amino radicals function equally as chemical modifiers for diamond surfaces (Column 11, lines 4-11). The courts have stated with regard to chemical homologs that the greater the physical and chemical similarities between the claimed species and any species disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner (see *Dillon*, 99 F.2d at 696, 16 USPQ2d at 1904). Therefore, one of skill in the art would be motivated to chemically modify the substrate of

Chrisey et al with a carboxyl radical based on the similar chemical and physical properties of polar radicals taught by Kobashi (Column 10, line 63-Column 11, line 11) because one skilled in the art would have expected the carboxyl radical to function in an equivalent manner. Additionally, the skilled practitioner would have been motivated to modify the diamond substrate of Chrisey et al with a carboxyl radical based on the teaching of Kobashi wherein a biomolecule is immobilized via carboxyl radical-modification of diamond substrate (Kobashi, Column 10, line 63-Column 11, line 11).

Response to Arguments

14. Applicant argues that Kobashi et al adds nothing to Chrisey. The argument has been considered but is not found persuasive for the reasons stated above regarding Chrisey.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
March 30, 2004